PATENT
Customer No. 22,852
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
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Michael Eppihimer, et al.	)	Group Art Unit: 1644
	)	
Serial No.: 09/825,580	)	Examiner: GAMBEL, P.
	)	
Filed: April 2, 2001	)	Confirmation No.: 9952
	)	
For: INHIBITION OF THROMBOSIS BY TREATMENT WITH P-SELECTIN ANTAGONISTS	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF DR. STEFAN HEMMERICH UNDER 37 C.F.R. § 1.132

I, Stefan Hemmerich, Ph.D., do hereby make the following declaration:

1. I am a senior scientist employed by Y's Therapeutics, Burlingame, CA. My curriculum vitae is attached to this declaration as Exhibit 1.

2. Y's Therapeutics is the licensee of U.S. Patent Application Serial No. 09/825,580, and thus, a party in interest in this application.

3. I have read the Office Action dated March 14, 2006, and I understand that the Examiner concludes that the disclosure of U.S. Patent No. 5,464,778 ("Cummings") in view of The Merck Manual of Diagnosis and Therapy (17th ed.) ("Merck Manual") anticipates the subject matter of claims 1-4, 8-13, 16-18, 25-27, 45-47, 50-53, and 57.

4. I have read the Office Action dated March 14, 2006, and I understand that the Examiner concludes that the disclosure of Cummings and U.S. Patent No.

5,840,679 ("Larsen") in view of Blann et al., "Evidence of platelet activation in hypertension," J. Hum. Hyper. 11:607-609 (1997) ("Blann"), U.S. Patent No. 6,150,348 ("Araneo"), U.S. Patent No. 5,604,207 ("DeFrees") and the Merck Manual render the subject matter of claims 1-20, 25-27, 31-40, 45, and 50-57 obvious to one of skill in the art at the time the invention was made.

5. I have read the Office Action dated March 14, 2006, and I understand that the Examiner concludes that the disclosure of Cummings and U.S. Patent No. 5,840,679 ("Larsen") in view of Blann, Araneo, DeFrees, the Merck Manual, Maugeri et al., "Polymorphonuclear Leukocyte-Platelet Interaction: Role of P-selectin in Thromboxane B2 and Leukotriene C4 Cooperative Synthesis," Thromb. Haem. 72:450-456 (1994) ("Maugeri") and Johnston et al., "Differential Roles of Selectins and the α4-Integrin in Acute, Subacute, and Chronic Leukocyte Recruitment In Vivo," J. Immunol. 159:4514-4523 (1997) ("Johnston") render the subject matter of claims 27 obvious to one of skill in the art at the time the invention was made.

Anticipation Rejection

6. I believe that the claimed methods are not disclosed expressly or inherently in Cummings or the Merck Manual.

7. Cummings discusses the use of P-selectin ligand for the treatment of atherosclerosis, injuries from ischemia and reperfusion, and that treatment of ischemia and reperfusion injury could indirectly treat stroke. (See column 18, line 59 to column 19, line 20). Cummings does not teach a method of inhibiting thrombosis in a subject having hypertension, and do not teach that atherosclerosis, strokes and injuries from ischemia and reperfusion are necessarily associated with hypertension.

8. The Merck Manual discusses the atherosclerosis, strokes and ischemia, but does not teach that these conditions are necessarily associated with hypertension. In fact, the Merck Manual merely indicates that there may be a correlation between hypertension and various conditions, but hypertension is just one of many risk factors that might predispose to certain conditions.

A. **Atherosclerosis**. The Merck Manual describes several risk factors for atherosclerosis including, age, male sex, family history, abnormal serum levels, hypertension, cigarette smoking, diabetes mellitus, obesity, physical activity and hyperhomocysteinemia. (See page 1656). The Merck Manual does not teach that hypertension is necessarily associated with atherosclerosis. The Merck Manual describes the differing properties of atherosclerotic arteries in patients with hypertension indicating that hypertension need not accompany atherosclerosis (See page 1655). Patients with atherosclerosis need not also have hypertension. This is well known by those skilled in the art.

B. **Stroke**. The Merck Manual teach that strokes can be caused by arteriosclerotic or hypertensive stenosis, thrombosis or embolism. (See page 1421). The Merck Manual does not teach that stroke is necessarily associated with hypertension. The Merck Manual teaches that hypertension is only one of several factors for diagnosing stroke, and that hypertension is one of three risk factors predisposing to stroke. (See page 1422; Also see page 1634). The Merck Manual

stresses distinguishing hypertension from other potential causes of stroke. (See page 1422). The Merck Manual indicates that a least one treatment of stroke should not be used when the patient is hypertensive. (See Table 174-3). Taken together, the Merck Manual indicates that hypertension and stroke do not always coexist. Patients suffering from a stroke do not always have hypertension. This is well known among those skilled in the art.

C. **Ischemia**. The Merck Manual teaches that a number of factors including hypertension predispose a patient to Transient Ischemic Attacks (TIA). The Merck Manual does not teach that hypertension is necessarily associated with TIA; however, and describes treatment for TIA for patients that are not hypertensive (See page 1421). The Merck Manual does not teach that TIA and hypertension are always present together. Patients having TIAs do not necessarily also have hypertension. The is well recognized by those skilled in the art.

9. Because hypertension is not necessarily associated with atherosclerosis, strokes and injuries from ischemia and reperfusion, one of ordinary skill in the art at the time the invention was made would not know whether a subject suffering from these conditions was also hypertensive. Accordingly, one of skill in the art at the time the invention was made could not envision that the treatments disclosed in Cummings were targeting patients with hypertension.

Obviousness Rejection

10. I believe that the claimed methods are not disclosed expressly or inherently in Cummings, Larsen, Blann, Araneo, DeFrees or the Merck Manual.

11. Larsen describes a P-selectin ligand protein, and methods of treating numerous conditions using P-selectin ligand (See column 15, lines 50-66). Larsen does not mention treatment of subjects with hypertension and does not mention treatment of thrombosis. Larsen does not teach that conditions that might be treated with P-selectin ligand are associated with hypertension and does not teach that a composition having P-selectin ligand activity could be used to treat or inhibit thrombosis, thrombus formation or deep vein thrombosis in a subject having hypertension. The disclosure in Larsen would not suggest to the skilled artisan that a composition having P-selectin ligand activity could be used to treat or inhibit thrombosis, thrombus formation or deep vein thrombosis in a subject having hypertension.

12. Blann investigates a potential correlation between platelet activation and hypertension (See page 607). Blann concludes that platelet activation in hypertension may provide a link between the risk factor hypertension and stroke (See abstract). Blann speculates that compounds that reduce platelet activity, such as aspirin, could be useful but does not teach or suggest that a composition having P-selectin ligand activity could be used to treat or inhibit thrombosis, thrombus formation, or deep vein thrombosis in a subject having hypertension. (See page 608). To one skilled in the art, the disclosure in Blann would not suggest that a composition having P-selectin ligand

activity could be used to treat or inhibit thrombosis, thrombus formation or deep vein thrombosis in a subject having hypertension.

13. Araneo discusses methods of preventing or reducing effects of ischemia and other conditions including pulmonary hypertension by administering the steroid DHEA. (See Abstract. Also see column 4). Araneo describes a reduction in expression of P-selectin upon treatment with DHEA. (See Example 6). Araneo does not teach that a composition having P-selectin ligand activity could be used to treat or inhibit thrombosis, thrombus formation, or deep vein thrombosis in a subject having hypertension, but suggests a treatment based on reducing the level of P-selectin expression. (See column 17, lines 59-64). To one skilled in the art, the disclosure in Blann would not suggest that a composition having P-selectin ligand activity could be used to treat or inhibit thrombosis, thrombus formation or deep vein thrombosis in a subject having hypertension.

14. DeFrees describes analogs of sialyl Le^x and speculates about the use of these compounds to treat inflammatory disorders. (See column 3 and column 44, lines 35-65). DeFrees mentions the use the of the sialyl Le^x analogs to treat deep vein thrombosis (See column 45, lines 7-15). However, DeFrees does not teach the treatment of deep vein thrombosis in a subject with hypertension and fails to suggest any relationship between P-selectin or PSGL-1 and the treatment of thrombosis in a subject with hypertension.

15. None of Cummings, Larsen, Blann, Araneo, DeFrees or the Merck Manual teach or suggest that a P-selectin ligand protein could be used to treat or inhibit thrombosis, thrombus formation or deep vein thrombosis in a subject having hypertension.

Obviousness Rejection of Claim 27

16. Maugeri investigates a relationship between LTC_4 and the aggregation of mixtures containing platelets and polymorphonuclear leukocytes, and describes decreased aggregation of these mixtures in the presence of an anti-P-selectin antibody *in vitro*. (See Introduction and Figure 2). Maugeri speculates about the importance of cell-cell interactions for production of LTC_4. (See page 455). Maugeri does not mention the use of a P-selectin ligand protein to treat thrombosis, and does not mention any relationship between thrombosis formation and hypertension. To one of ordinary skill in the art, the disclosure of Maurgeri would not suggest a method of treating or inhibiting thrombus formation induced by a thrombus-inducing agent in a subject comprising identifying a subject having hypertension and administering to the subject a composition of a PSGL-1 protein, or said method wherein the thrombus inducing agent is LTC_4.

17. Johnston investigates the ability of anti-P-selectin antibodies to inhibit LTC_4-induced leukocyte rolling *in vitro* (See e.g. Figure 1). Johnston describes the use of an anti-P-selectin antibody to reduce leukocyte rolling. (See e.g. Figure 2). Johnston speculates about anti-inflammatory strategies designed to block leukocyte recruitment but does not identify the use of a P-selectin protein. (See page 4532). Moreover, Johnston fails to teach or suggest any relationship between thrombus formation and

hypertension. To one of ordinary skill in the art, the disclosure of Johnston would not suggest a method of treating or inhibiting thrombus formation induced by a thrombus-inducing agent in a subject comprising identifying a subject having hypertension and administering to the subject a composition of a PSGL-1 protein, or said method wherein the thrombus inducing agent is LTC_4.

18. Neither Maugeri nor Johnston teach or suggest the use of a P-selectin ligand protein to treat thrombosis, and do not teach that hypertension is necessarily associated with thrombosis. These publications alone, or when combined with Cummings, Larsen, Blann, Araneo, DeFrees, or the Merck Manual would not render the claimed method obvious to one of skill in the art at the time the invention was made.

Dated: September 13, 2006

By: _____
Stefan Hemmerich, Ph.D.
Senior Scientist
Y's Therapeutics

Curriculum Vitae

NAME	POSITION TITLE
Stefan Hemmerich	Senior Scientist

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of Heidelberg, Heidelberg, Germany	B.Sc.	1979-1983	Chemistry
Weizmann Institute of Science, Rehovot, Israel	Ph. D.	1984-1989	Life Sciences
Rockefeller University, New York City, NY	postdoctoral	1990	Cell Biology
University of California, San Francisco, CA	postdoctoral	1990-1993	Immunology

A. Positions and Honors

Positions and Employments

1993-1995	Research Scientist, Syntex Inc., Palo Alto, CA.
1995-2000	Research Scientist and Program Leader, Roche Bioscience, Palo Alto, CA.
2000-2002	Senior Scientist – First Employee, Thios Biotechnology, Oakland, CA.
2002-2004	Head, Department of Target Validation, Thios Pharmaceuticals, Emeryville, CA.
11/04-7/05	Consultant for Selexys Pharmaceuticals, Oklahoma City, OK, and Antibody Solutions, Mountain View, CA.
7/05-present	Senior Scientist, Y's Therapeutics, Burlingame, CA.

Other Experiences and Professional Memberships.

1994-2000	Reviewer, Grant Review Board Vascular Biology II, American Heart Association.
1993-present	Member, American Association for the Advancement of Science.
2003-present	Member, Society for Glycobiology.

Awards and Grants

1984-1986	Minerva Foundation Fellowship
1990-1992	German Research Council Fellowship.
2002	Principal Investigator, SBIR grant 1R43AI51059-01 (NIH-NIAID) to Thios Pharmaceuticals.
2003	Principal Investigator, SBIR grant 1R43AI55108-01 (NIH-NIAID) to Thios Pharmaceuticals.

A. Patents

Stefan Hemmerich and Israel Pecht, "Cromolyn binding protein in highly purified form and methods for the isolation thereof", U.S. Patent 4,996,296 (February 26, 1992).

Steven D. Rosen, Stefan Hemmerich and Yasuyuki Imai, "Treating inflammation via the administration of specific sulfatase enzymes and/or sulfation inhibitor", U.S. Patents 5,695,752 (December 9, 1997) and 5,925,349 (July 20, 1999), European Patent 0,750,511 (June 11, 2003).

Steven D. Rosen and Stefan Hemmerich, "Sulfated Ligands for L-Selectin and Methods for Treating Inflammation", U.S. Patent 5,489,578 (February 6, 1996).

Annette Bistrup, Steven D. Rosen, Kirsten Tangemann and Stefan Hemmerich, "Glycosyl Sulfotransferase-3", U.S. Patent 6,265,192 (July 24, 2001).

Annette Bistrup, Steven D. Rosen, Kirsten Tangemann and Stefan Hemmerich, "Method of Determining whether an agent modulates Glycosyl Sulfotransferase-3", U.S. Patent 6,365,365 (April 2, 2002).

Annette Bistrup, Steven D. Rosen, Kirsten Tangemann and Stefan Hemmerich, "Methods of inhibition using Glycosyl Sulfotransferase-3", U.S. Patent 6,844,175 (January 18, 2005).

Steven D. Rosen, Jin Kyu Lee and Stefan Hemmerich, "Glycosyl sulfotransferases GST-4 alpha, GST-4 beta, and GST-6", U.S. Patents 6,852,518 (February 8,2005) and 7,070,971 (July 4, 2006).

Annette Bistrup, Steven D. Rosen, and Stefan Hemmerich, "HEC-GlcNAc6ST", U.S. Patent 6,933,142 (August 23, 2005).

Annette Bistrup, Steven D. Rosen, and Stefan Hemmerich, " Glycosyl sulfotransferase-3", U.S. Patent 6,967,093 (November 22, 2005).

Additional U.S. and foreign patent applications pending.

B. Peer-Reviewed Publications (in chronological order)

(Total of 33 peer-reviewed publications)

Stefan Hemmerich and Israel Pecht (1988), "Isolation and Purification of an Fc_{ε}-Receptor Activated Ion Channel from the Rat Mast Cell Line RBL-2H3," Biochemistry 27, 7488-7498.

Ayus Corcia, Israel Pecht, Stefan Hemmerich, Sophia Ran and Benjamin Rivnay (1988), "Calcium Specificity of the Antigen-Induced Channels in Rat Basophilic Leukemia Cells", Biochemistry 27, 7499-7506.

Stefan Hemmerich, Dorothea Sijpkens and Israel Pecht (1991), "A Novel Cell-Permeable Cromoglycate Derivative Inhibits Type I Fc_{ε}Receptor-Mediated Ca^{2+}-Influx and Mediator Secretion in Rat Mucosal Mast Cells", Biochemistry 30, 1523-1532.

Stefan Hemmerich, Yosef Yarden and Israel Pecht (1992), "A Cromoglycate Binding Protein from Rat Mast Cells of a Leukemia Line Is a Nucleoside Diphosphate Kinase", Biochemistry 31, 4574-4579.

Stefan Hemmerich and Israel Pecht (1992), "Oligomeric Structure and Auto-phosphorylation of Nucleoside Diphoshate Kinase from Rat Mucosal Mast Cells", Biochemistry 31, 4580-4587.

Susanne Baumhüter, Mark S. Singer, William Henzel, Stefan Hemmerich, Mark Renz, Steven D. Rosen and Laurence A. Lasky (1993), "Binding of L-Selectin to the Vascular Sialomucin CD34", Science 262, 436-438.

Stefan Hemmerich, Carolyn R. Bertozzi, Hakon Leffler and Steven D. Rosen (1994), "Identification of the Sulfated Monosaccharides of GlyCAM-1, an Endothelial Ligand for L-Selectin", Biochemistry 33, 4820-4829.

Stefan Hemmerich and Steven D. Rosen (1994), "6'-Sulfated Sialyl Lewis x Is a Major Capping Group of GlyCAM-1", Biochemistry 33, 4830-4835.

Stefan Hemmerich, Eugene C. Butcher and Steven D. Rosen (1994), "Sulfation-Dependent Recognition of Three HEV-Ligands by L-Selectin and MECA-79, an Adhesion-Blocking Monoclonal Antibody", J. Exp. Med. 180, 2219-2226.

Stefan Hemmerich, Hakon Leffler and Steven D. Rosen (1995), "Structure of the O-Glycans in GlyCAM-1, an Endothelial Ligand for L-Selectin", J. Biol. Chem. 270, 12035-12047.

Kendra G. Bowman, Stefan Hemmerich, Sunil Bakhta, Mark S. Singer, Steven D. Rosen and Carolyn R. Bertozzi (1998), "Identification of an N-Acetylglucosamine-6-O-Sulfotransferase Activity Specific to Lymphoid Tissue: An Enzyme With A Possible Role In Lymphocyte Homing", Chemistry and Biology 5, 447-460.

Chad Paavola, Stefan Hemmerich, Dorit Grunberger, Irene Polsky, Adam Bloom, Richard Freedman, Mary Mulkins, Sunil Bhakta, Deborah McCarley, Ludwig Wiesent, Belinda Wong, Kurt Jarnagin and Tracy Handel (1998), "Monomeric MCP-1 Binds and Activates the MCP-1 Receptor CCR2-B", J. Biol. Chem. 273, 33157-33165.

Annette Bistrup, Sunil Bhakta, Jin Kyu Lee, Yevgeniy C. Belov, Michael Dee Gunn, Feng-Rong Zuo, Chiao-Chain Huang, Reiji Kannagi, Steven D. Rosen and Stefan Hemmerich (1999), "Sulfotransferases of Two Specificities Function in the Reconstitution of High-Endothelial-Cell Ligands for L-Selectin", J. Cell Biol. 145:899-910.

Stefan Hemmerich, Chad Paavola, Adam Bloom, Sunil Bhakta, Richard Freedman, Dorit Grunberger, John Krstenansky, Simon Lee, Debbie McCarley, Mary Mulkins, Belinda Wong, Joe Pease, Laura Mizoue, Tara

Mirzadegan, Irene Polsky, Kelly Thompson, Tracy M. Handel and Kurt Jarnagin (1999), "Identification of Residues in The Monocyte Chemotactic Protein-1 that Contact the MCP-1 Receptor, CCR-2", Biochemistry 38, 13013-13025.

Jin Kyu Lee, Sunil Bhakta, Steven D. Rosen and Stefan Hemmerich (1999), "Cloning and Characterization of a Mammalian N-Acetylglucosamine-6-Sulfotransferase that is Highly Restricted to Intestinal Tissue", Biochem. Biophys. Res. Comm. 263, 543-549.

Kirsten Tangemann, Annette Bistrup, Stefan Hemmerich and Steven D. Rosen (1999), "Sulfation of GlyCAM-1: Effects on the Kinetics of L-Selectin Interactions", J. Exp. Med. 190, 935-941.

Kurt Jarnagin, Dorit Grunberger, Mary Mulkins, Belinda Wong, Stefan Hemmerich, Chad Paavola, Adam Bloom, Sunil Bhakta, Frank Diehl, Richard Freedman, Debbie McCarley, Irene Polsky, Ann Ping-Tsou, Alan Kosaka and Tracy M. Handel (1999), "Identification of Surface Residues of the Monocyte Chemotactic Protein-1 that Effect Signaling Through the MCP-1 Receptor, CCR-2", Biochemistry 38, 16167-16177.

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Brian Cook, Sunil Bhakta, Teresa Biegel, Kendra G. Bowman, Josh I. Armstrong, Stefan Hemmerich and Carolyn R. Bertozzi (2000), "Differential substrate requirements of GlcNAc-6-sulfotransferases", J. Am. Chem. Soc. 122, 8612-8622.

Stefan Hemmerich and Steven D. Rosen (2000), "Carbohydrate Sulfotransferases in Lymphocyte Homing", Glycobiology 10, 849-856.

Steven D. Rosen, Annette Bistrup and Stefan Hemmerich (2000), "Carbohydrate Sulfotransferases", in: Oligosaccharides in Chemistry and Biology. Edited by B. Ernst, P. Sinaÿ and G. Hart. Weinheim: Wiley-VCH, vol. 2. pp. 245-260.

Sunil Bhakta, Alexander Bartes, Kendra G. Bowman, Irene Polsky, Jin-Kyu Lee, Wei-Ming Kao, Brian N. Cook, Richard E. Bruehl, Carolyn R. Bertozzi, Steven D. Rosen and Stefan Hemmerich (2000), " Sulfation of N-Acetylglucosamine by Chondroitin 6-O-Sulfotransferase-2", J. Biol. Chem. 275, 40226-40234.

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Stefan Hemmerich, Jin Kyu Lee, Sunil Bhakta, Annette Bistrup, Nancy R. Ruddle and Steven D. Rosen (2001), "Chromosomal Localization and Genomic Organization for the Galactose/N-Acetylgalactosamine/N-Acetylglucosamine 6-O-Sulfotransferase Gene Family", Glycobiology 11, 75-87.

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Stefan Hemmerich (2002), "Intestinal N-Acetylglucosamine 6-0-sulfotransferase", in: Handbook of Glycosyltransferases and Their Related Genes. Edited by N. Taniguchi and M. Fukuda. Tokyo: Springer Verlag, pp. 434-438.

Stefan Hemmerich, Annette Bistrup, Mark S. Singer, Annemieke van Zante, Jin Kyu Lee, Durwin Tsay, Meredith Peters, Janet L. Carminati, Thomas J. Brennan, Karen Carver-Moore, Michael Leviten, Maria E. Fuentes, Nancy H. Ruddle and Steven D. Rosen (2001), "Sulfation of L-Selectin Ligands Regulates Lymphocyte Homing to Lymph Nodes", Immunity 15, 237-247.

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Diana Palmeri, Feng-Rong Zuo, Steven D. Rosen, and Stefan Hemmerich (2004). "Differential gene expression profile of human tonsil high endothelial cells: implications for lymphocyte trafficking". J. Leukoc. Biol. 75, 910-927.

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Virginia L. Rath, Dawn Verdugo, and Stefan Hemmerich, (2004), "Sulphotransferase Structural Biology and Inhibitor Discovery", Drug Discovery Today 9, 1003-1011.

Stefan Hemmerich, (2005), "Glycomics: coming of age across the globe", Report from US/Japan Glyco 2004, Joint Meeting of the Society for Glycobiology and the Japanese Society of Carbohydrate Research, November 17-20, 2004, Honolulu, HI,, Drug Discovery Today Drug 10, 307-309.

Steven D. Rosen, Durwin Tsay, Mark S. Singer, Stefan Hemmerich, and William M. Abraham (2005). "Therapeutic Targeting of Endothelial Ligands for L-Selectin (PNAd) in a Sheep Model of Asthma". Am. J. Pathol. 166, 935-44.

Jiwei Yang, Steven D. Rosen, Phillip Bendele, and Stefan Hemmerich (2006). "Induction of PNAd and N-acetylglucosamine 6-O-sulfotransferases 1 and 2 in mouse collagen-induced arthritis". BMC Immunology 2006, 7:12.

Stefan Hemmerich, (2006), "Protein Sulfation", in: "Handbook of Neurochemistry and Molecular Neurobiology", Abel Lajtha, editor, Kluwer Publishing Corporation, New York, NY, in press.